

### REMARKS

Claims 1-43 have been cancelled. Claims 44 and 45 have been amended to address issues raised by the Examiner as discussed below. No new matter has been added herewith.

#### **Compliance with 35 U.S.C. 112, first paragraph (Written description)**

The Examiner rejected claims 1-4, 6-8, 10-11, 17-18, and 40-45 on the basis that they lack written description in the Specification. Cancellation of Claims 1-43 by amendment herein renders this rejection moot as to those claims. The terms “variants”, “truncated variants”, and references to “60% sequence identity”, “homologues and derivatives” have all been removed from the pending claims.

In addition, Claims 44 and 45 have been amended to unambiguously recite “An isolated, recombinant immunogenic polypeptide comprising an amino acid sequence as set forth in SEQ ID NO: 1” and “...composition comprising the isolated recombinant immunogenic polypeptide of SEQ ID NO: 1”. Accordingly, presently pending Claims 44 and 45 have clear written description support and are therefore in compliance with 35 U.S.C. 112, first paragraph.

#### **Compliance with 35 U.S.C. 112, first paragraph (Enablement)**

The examiner rejected claims 1-4, 6-8, 10, 11, 13-14, 17-20, and 40-45 on the basis that they are not enabled by the Specification. The Examiner noted on page 10 of the Final Office Action:

“It is the position of the Examiner that the specification discloses an isolated recombinant polypeptide comprising the amino acid sequence, SEQ ID NO: 1 and is immunogenic therefore, applicants are enabled for an immunogenic composition comprising the amino acid sequence SEQ ID NO: 1, wherein the isolated polypeptide, when administered to a subject in a suitable composition which can include an adjuvant, or suitable carrier coupled to the polypeptide, induces an antibody or T-cell response that recognizes the polypeptide SEQ ID NO: 1.”

In accordance with the scope of enablement recognized by the Examiner, Claim 44 has been amended to clearly and distinctly claim “An isolated recombinant, immunogenic polypeptide comprising an amino acid sequence as set forth in SEQ ID NO: 1”. Similarly, Claim 45 has been amended to clearly and distinctly claim “A vaccine composition for the prophylaxis or treatment of infection of an animal by *Lawsonia spp.*, said vaccine composition comprising the isolated, recombinant immunogenic polypeptide of SEQ ID NO: 1”. Claims 44 and 45 are enabled by the Specification and are therefore in compliance with 35 U.S.C. 112, first paragraph.

### Compliance with 35 U.S.C. § 102(b)

The Examiner rejected claims 1-4, 6-8, 10, 11, 13-14, 17-18 and 40-45 under 35 U.S.C. § 102(b) as being anticipated by McOrist et al. 1989 *Infect Immunol* 57:957-962. The Examiner maintained that the previously claimed polypeptide and composition and the polypeptide and composition of the prior art are the same. Cancellation of claims 1-43 and amendment of claims 44 and 45 to specifically direct the claims to polypeptide comprising amino acid sequence as set forth in SEQ ID NO: 1 makes this rejection moot because remaining claims 44 and 45 no longer read on the prior art.

The Examiner also rejected claims 1-4, 6-8, 10, 11, 13-14, 17-18 and 40-45 under 35 U.S.C. § 102(b) as being anticipated by Panaccio M. et al., Database: A Geneseq and Accession number AAW16680, WO9720050-A1. Panaccio discloses SEQ ID No: 7 which the Examiner asserts is a variant or homologue of FlgE. Cancellation of Claims 1-43 by amendment herein renders this rejection moot as the terms "variants", "truncated variants", and references to "60% sequence identity", "homologues and derivatives" have all been removed from the pending claims. Claims 44 and 45 are, therefore, in compliance with 35 U.S.C. § 102(b). In accordance with the foregoing, Applicants respectfully request removal of the rejections over the prior art.

### Conclusion

In view of Applicants' amendments to the Specification and the Claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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